UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR - 6 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Irgaguard B5000: Request for assessment of risk from proposed food contact uses of the active ingredient.

EPA Identification Numbers:

P.C. Code:072501
DP Barcodes:D287537; D287389

EPA Reg. No. 40810-18
Submissions: S625817

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Action Requested: Determination of dietary risk from food and drinking water contact uses of Irgaguard® B5000.

The registrant (Ciba Specialty Chemicals) has submitted a letter with supporting documentation (consisting of a cited data matrix and a review of Toxicological data for silver and zinc) whose purpose is to seek approval for use of Irgaguard® B5000 (containing 0.44% elemental silver and 1.36% elemental zinc) for use in the manufacture of polymer, plastic, and textile products. No public health claims are to be made on the finished products. Several of the use sites for the finished products as listed on the proposed label include sites where indirect food contact will occur (countertops, appliances, kitchen hardware, tiles, food trays, food processing equipment, food storage containers, food packaging, food processing utensils) as well as water contact (tubing, plumbing supplies and fixtures). There are also numerous uses in fibers where dermal contact is expected, including apparel items and interior furnishings. This list is not meant to be all-inclusive but highlights the risk issues to be considered. Due to the potential for food contact with the pesticide, a dietary risk assessment will be required.

The registrant for the present submission has cited data previously submitted and reviewed by the Agency in support of their application, and has also requested a waiver for conduct of toxicology studies that are required for indirect food uses of antimicrobial pesticides (subchronic toxicity testing in the rodent, subchronic toxicity testing in the non-rodent, reproductive toxicity testing in the rodent). The studies cited by the registrant are as follows:

Guideline Number	Data Requirement	MRID Number	Status
870.1100	Acute Oral Toxicity	45618604	acceptable
870.1200	Acute Dermal Toxicity	45618605	acceptable
870.1300	Acute Inhalation Toxicity	45618606	acceptable
870.2400	Primary Eye Irritation	45618607	acceptable
870.2500	Primary Dermal Irritation	45618608	acceptable
870.2600	Dermal Sensitization	45618609	acceptable
870.3100	Subchronic Oral Toxicity-Rodent	waiver request	not acceptable
870.3250	Subchronic Dermal Toxicity-Rodent	41615807	not acceptable
870.3150	Subchronic Oral Toxicity-Non-rodent	waiver request	not acceptable
870.3700	Developmental Toxicity in Rats	41638502	not acceptable
870.3800	Reproductive Toxicity in Rats	waiver request	not acceptable
870.5100	Ames Salmonella reverse mutation assay	42032803	acceptable
870.5380	In vivo chromosome aberration assay	42032804	acceptable

870.5300	In vivo Cytogenetics	42820101	acceptable

Conclusions

Of the data cited above by the registrant, it is noted that the acute toxicity studies are new and have been reviewed and found acceptable. However, the MRID numbers cited for the subchronic dermal toxicity study and the developmental toxicity study are for a silver-copper product, not a silver-zinc product. These studies are thus not applicable to this application and cannot be used in support of it. The mutagenicity studies cited are appropriate to the product.

With respect to the registrant's conclusion that "there are adequate, scientifically valid data available on zinc and silver to assess the potential toxicological risks associated with indirect food contact uses of pesticides containing these compounds," the registrant should be aware that the Antimicrobials Division, through consultation with the Health Effects Division Hazard Identification Assessment Review Committee, determined that from examination of the data in the silver RED document,... the studies cited in the RED were inadequate for hazard identification and risk assessment." New studies based on data requirements as drafted in 158 Subpart W were required. The registrant should also be aware that the Antimicrobials Division has requested and has received toxicology data from other registrants of silver-based products for similar uses. The Antimicrobials Division has not relieved other registrants of their obligation of fulfilling the necessary data requirements for food contact uses of silver based antimicrobial pesticides.

Based on the current registrant's reluctance to compensate other registrants for citation of required data in support of their application, the request for use of the Irgaguard® B5000 product in food and water contact sites is <u>not</u> toxicologically supported, and a dietary risk assessment cannot be conducted for this product based on the available data. The registrant must submit or cite valid toxicology studies conducted with the end-use formula silver-zinc product for subchronic toxicity in the rodent, subchronic toxicity in the non-rodent, developmental toxicity in the rodent, and reproductive toxicity in the rodent. Separate toxicity studies with technical grade silver and technical grade zinc are not required, but toxicity data on the formula with the highest percentage of silver and zinc should be conducted. This will support other end-use formulations from the registrant containing lower percentages of silver and zinc.